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EXAMINER	
KRSEK-STAPLES, J	
ART UNIT	PAPER NUMBER
1813	22

DATE MAILED: 07/10/95

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☑ THE PERIOD FOR RESPONSE:

a) ☑ is extended to run 6 months or continues to run _____ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☑ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☑ Applicant's response to the final rejection, filed 6-7-95 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☑ Upon the filing an appeal, ~~the proposed amendment ☐ will be entered ☐ will not be entered~~ and the status of the claims will be as follows:

   Claims allowed: _____
   Claims objected to: _____
   Claims rejected: 1, 2

   However;

   ☐ Applicant's response has overcome the following rejection(s): _____

4. ☑ The ~~affidavit~~, exhibit or request for reconsideration has been considered but does not overcome the rejection because See attached

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☑ Other 2 Interview Summaries enclosed

[illegible] SIDBERRY
PRIMARY EXAMINER
GROUP 1800

PTOL-303 (REV. 5-89)

Attachment to Advisory Action

Applicants again argue that it is the totality of the evidence that 1) the Recognin antibody titer is reduced following tumor removal and 2) *in vitro* data that demonstrate the cytotoxicity of anti-recognin antibodies which establishes that Recognins elicit protective immunity to cancer. This argument has been presented in the response filed 3/15/95 and has been addressed in the Advisory Action dated 4/18/95.

In the interview on 5/16/95 it was discussed that scientific literature which showed a similar fact pattern regarding actuarial survival data and *in vitro* cytotoxic activity of another tumor antigen which resulted in protection when tested in an animal model would be considered as a possible correlation of the current facts presented about Recognin and its ability to provide protective immunity against cancer. The abstracts submitted by Applicants have been considered. (Note that only the first page of Abstract S13 discussed in the response was received. It appears that pages are missing because the last paragraph ends in the middle of a sentence). These abstracts discuss various tumor associated antigens. Specifically, Abstract S08 discusses specific peptide motifs which bind to major histocompatibility (MHC) class I molecules and which may be used to induce specific cytotoxic T lymphocytes directed against cancer. Abstract S13 discusses the use of recombinant and synthetic peptide vaccines which have been tested in murine models. While tumor associated antigens and synthetic peptides have been tested in murine models and the abstracts demonstrate the importance of the T cell response in treating cancer, none of the abstracts show a correlation with results similar to those observed with Recognin (i.e. a correlation with increased antibodies and survival in patients and *in vitro* inhibition of cancer

cell growth) and protection against cancer in an animal model. Therefore, these exhibits are not sufficient to overcome the rejection set forth under 35 U.S.C. §112, first paragraph.

JKS

Julie Krsek-Staples, Ph.D.
July 10, 1995

HAZEL F. SIDBERRY
PRIMARY EXAMINER
GROUP 1800